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Second Medical Use Claims Knockin' on Dutch Supreme Court's Door

Rik Lambers (Brinkhof) · Thursday, October 6th, 2016

In 2010 the EPO's Enlarged Board of Appeal took the badge of Swiss type claims from patentees (G 02/08), and since then they cannot use it anymore. Six years later two cases on (infringement of) Swiss type / second medical use claims are knockin' on the Dutch Supreme Court's door. While the Enlarged Board put Swiss type claims in the ground, patentees can still use them to shoot Generics. (By now the obvious reference must be obvious to the reader).

Actually, three second medical use cases of note have made it through the Dutch courts recently. One concerns the *MSD / Teva* litigation over the use of ribavirin for the manufacture of a pharmaceutical composition for treating a specific sub-group of patients having chronic hepatitis suffering from HCV-infection. In that case the Dutch Court of Appeal (July 15, 2015), i.a., considered that the Swiss form claim

> *provides protection against the use of the compound for the treatment of the 'new' disease. […] the scope of protection can encompass […] the trade in the compound by a third party […].*

As to direct infringement of Swiss type claims, the Court of Appeal considered:

> *The court of appeal will assume that there is a situation of direct infringement in the case at hand, for example because the scope of protection of a Swiss type claim – which concerns a process – covers, on the basis article 64 (2) EPC the directly obtained results […].*

The Court of Appeal decided that, in view of (the carve outs in) Teva's SmPC and patient leaflet, there was no direct or indirect infringement, aside from the questions whether physicians or pharmacists prescribed, sold or supplied the Teva's generic ribavirin for the patented use (treatment of a G1N-subgroup). The *MSD / Teva* case was pleaded before the Supreme Court last Friday. Rounds of legal briefs, and an opinion of the Advocate General ('AG', the Supreme Court's advisor or – to stay in tune with the introduction of this post – gatekeeper of legal heaven's doors) will follow, so a decision cannot be expected in the near future.

The other two cases concern the *Novartis / Sun* litigation over Novartis' patent related to the (second medical) use of zoledronic acid in the preparation of a medicament for the treatment of osteoporosis. Sun marketed its generic version of zoledronic acid for the treatment of Paget's disease and requested a carve out for the indication for osteoporosis in light of Novartis' patented second medical use. However, Sun won a tender from a health insurer in which no distinction was made between Paget's disease or osteoporosis. Sun's generic product was therefore not only prescribed for Paget's disease (an expected 2,7%), but also for osteoporosis (an expected 97,3%) as a result of the health insurer's policy.

According to Novartis Sun's generic medicament was in practice actually prescribed for the treatment of osteoporosis and claimed indirect patent infringement by Sun. According to Novartis, Sun infringed its patent due to the fact that its generic product was marked for the treatment of osteoporosis numerous times in the supply chain. Sun should have known that this would happen and nonetheless offered the generic product for sale.

The Court of Appeal decided the case in PI proceedings in January 2015 and granted Novartis an injunction based on indirect infringement. The Court of Appeal did not provide a specific construction of the Swiss type claim at issue (though in the subsequent *MSD/Teva* decision it could be derived the Court of Appeal may construe Swiss type claims as purpose limited product claims). The Court of Appeal did consider in *Novartis/Sun* – i.a. in view of the ratio of patients suffering from Paget's disease and patients suffering from osteoporosis – that it could virtually be ruled out that Sun's genericproduct was not delivered and used for osteoporosis. The Court of Appeal considered as regards indirect infringement[1]:

> *Sun should therefore know that its product will also be delivered for the patented indication at the end of the vertical marketing chain. […] After a preliminary assessment the requirement for accepting indirect infringement, Sun's knowledge of infringing use of its Generic Product, is therefore fulfilled.*

The *Novartis/Sun* case was also considered by the Hague District Court in subsequent *merits* proceedings (interim decision of November 2015). The District Court noted that the TBA construed Swiss type claims as purpose limited process claims, while EPC 2000 claims were construed as purpose limited product claims (T 1780/12). The District Court (therefore) construed Novartis' Swiss type claim at issue as a process claim and considered and that there could not be indirect infringement as there is no preparation in the vertical chain after Sun has delivered the product. The District Court did not yet decide whether the direct result of the process (the medicament) is protected and there could be a direct infringement.

In its decision the District Court took account of – and came to the same conclusion as – the UK High Court's *Warner-Lambert v Activis* decisions (Lyrica – January 2015). In view of this decision, and the subsequent UK Court of Appeal decision (May 2015) and UK High Court decision (September 2015), the court allowed the parties to file further briefs on *direct* infringement of the Swiss type claim. A subsequent (final) decision has not yet been rendered by the District Court.

However, most recently, the Supreme Court's AG (mr. Van Peursem) has provided his opinion on the Court of Appeal's *Novartis / Sun* decision (opinion of September 30, 2016). The AG considers

that there is no European consensus on the question whether indirect infringement of a Swiss type claim is even possible (i.a. referring to the post on this blog on the Barcelona Court). However, since this question is not part of the Supreme Appeal, the AG takes as a starting point that such infringement is legally possible. The Advocate General therefore focuses his opinion on the question whether Sun's carve out (a.k.a. skinny labeling) should be considered a sufficient measure to excuse itself from alleged knowledge of patented use of its generic product (i.e. use for osteoporosis).

The AG considers that a carve out as such may not be sufficient in the circumstances of a case, especially in given the practice of cross label use. In this case, the AG considers the circumstances to be detrimental to Sun's position, e.g. the preference policy of the health insurer, Sun's unconditional and unlimited obligation to supply its generic product, the (known) practice of medical professionals and pharmacists, the (dis)balance between patients suffering from Paget's disease and osteoporosis. In view of those circumstances Sun should have know that at the end of the supply chain would also be supplied and used for the patented use. The AG i.a. considers that Sun's measures do not need to prevent infringing use entirely, but that it would be sufficient for Sun to make infringing use more difficult (which it did insufficiently). To prevent cross label use Sun, as the Court of Appeal considered, should have put effort in the moving the health insurer to make a distinction between the indication of the medicament (e.g. Paget's disease, or osteoporosis). All in all the AG dismisses Sun's grounds of supreme appeal against the Court of Appeal's decision (including grounds touching on the interplay between patent law and competition law, and patent law and (other) fundamental rights).

In the *Novartis/Sun* case the Swiss type claim has now passed the AG and entered the Supreme Court's chambers for consideration; the *MSD / Teva* case is to follow. While given the badge for years by the Enlarged Board, no long black cloud is comin' down on Swiss type claims for years to follow in national proceedings.

[1] The Dutch Court of Appeal – as the District Court in the merits case – considered that Novartis could claim priority and therefore did consider indirect infringement, other than the UK High Court (15 March 2013) and Court of Appeal (19 December 2013) in *Hospira v Novartis*. The UK Courts considered Novartis' patent invalid due to lack of novelty.

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